4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0547]

Guidance for Industry on Abbreviated New Drug Applications: Stability Testing of Drug Substances and Products, Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers." It replaces the draft guidance with the same name that published on August 27, 2013 (78 FR 52931). This guidance clarifies stability testing recommendations discussed in International Conference on Harmonisation (ICH) stability guidances Q1A(R2) through Q1E for abbreviated new drug applications (ANDAs) and provides responses to public comments in a questions-and-answers format.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Radhika Rajagopalan, Center for Drug Evaluation and Research (HFD-640), Food and Drug Administration, 7500 Standish Pl., MPN2, rm. 243, Rockville, MD 20855, 240-276-8546.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers." Because of increases in the number and complexity of ANDAs and FDA's desire to standardize generic drug review, on September 25, 2012 (77 FR 58999), FDA published a draft and on June 20, 2013 (78 FR 37231), published a final guidance entitled "ANDAs: Stability Testing of Drug Substances and Products" recommending that the generic industry follow the approach to stability testing outlined in the ICH stability-related guidances: (1) "Q1A(R2) Stability Testing of New Drug Substances and Products," November 2003; (2) "Q1B Photostability Testing of New Drug Substances and Products," November 1996; (3) "Q1C Stability Testing for New Dosage Forms," May 1997; (4) "Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products," January 2003; and (5) "Q1E Evaluation of Stability Data," June 2004. These guidances can be found on the FDA Guidances (Drugs) Web site under International Conference on Harmonisation--Quality at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm065005.h

tm. FDA also recommended that industry follow the ICH outlined definitions, glossaries, references, and attachments.

To more effectively address the public comments on the September 2012 draft guidance on "ANDAs: Stability Testing of Drug Substances and Products," we decided to publish a draft guidance in a questions-and-answers format entitled "ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers." The draft of this guidance published on August 27, 2013 (78 FR 52931). We have carefully considered the comments we received on that draft, have updated the draft guidance as appropriate, and are now announcing the availability of the final guidance for industry entitled "ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers" that supersedes the draft.

This guidance discusses general issues, drug master files, drug product manufacturing and packaging, amendments to pending ANDA applications, and stability studies, with the intent of clarifying the stability testing data recommendations for ANDAs. In addition, the guidance addresses comments received on the August 2013 draft.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on stability testing of drug substances and products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the

docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

III. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910-0014 and 0910-0001, respectively.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: May 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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